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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|------------------------------|---------------------|------------------|
| 10/764,730 | 01/26/2004 | Hans Konrad Muller-Hermelink | 50308/009002 | 8646 |
| 21559 | 7590 | 06/20/2006 | EXAMINER | |
| CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110 | | | HALVORSON, MARK | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1642 | |
| DATE MAILED: 06/20/2006 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|-------------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/764,730 | MULLER-HERMELINK ET AL. | |
| | Examiner | Art Unit | |
| | Mark Halvorson | 1642 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) 1-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 55-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/29/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group XIII, claims 55-57, is acknowledged and has been entered. Claims 1-57 are pending in the application and Claims 1-54 have been withdrawn from further consideration by the examiner under 37 C.F.R. 1.142(b) as being drawn to non-elected inventions. Claims 55-57 are currently under prosecution.

Priority

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. §120 and 365(c) as follows:

A certified copy of the international application (and an English translation) of the international application may be required by the examiner to perfect the claim for benefit under 35 U.S.C. 120 and 365(c) if the international application did not originate in the United States and such is necessary, for example, where an intervening reference is found and applied in a rejection of one or more claims. Thus, the filing date of foreign priority documents are not perfected unless applicant has filed a certified priority document in the application (and an English language translation, if the document is not

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in English) (see 37 CFR 1.55(a)(3)) and the examiner has established that the priority document satisfies the enablement and description requirements of 35 U.S.C. 112, first paragraph. MPEP 706.02(b).

Particularly, there is no certified copies for foreign priority documents DE 101 36 009.6 and DE 102 10 425.5 and no translations for priority documents PCT/DE02/02699, DE 101 36 009.6 and DE 102 10 425.5.

Thus, claims 55-57 are hereby assigned the priority date of **January 26, 2004**, the filing date of the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 56 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 56 recites "said fragment comprises amino acids 469-518 of SEQ ID NO:6 and the amino acids 739-748 of SEQ ID NO:6". It is not clear if the fragment comprising amino acids 469-518 and 739-748 consists of a fragment with the two amino acid sequences directly adjacent to each other or separated by other amino acids. Further it is not clear if the fragment comprising amino acids 469-518 and amino acids 739-748 consists of a contiguous peptide fragment of SEQ ID NO:6.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 57 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the adenocarcinoma cell line 23132 (DSMZ Accession No. DSM ACC 201) is required to practice the invention. As such, the adenocarcinoma cell line 23132 must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the adenocarcinoma cell line 23132. In the instant case, there is no information in the specification about the deposit of adenocarcinoma cell line 23132 or whether the cell line is readily available to the public.

If a deposit is made under the terms of the Budapest Treaty, Applicant must state that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address. (See 37 C.F.R. § 1.803). Furthermore, an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released to the public upon the

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issuance of a patent, would satisfy the deposit requirement made herein. If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that:

- a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;
- b) all restrictions upon availability to the public will be irrevocably removed upon the granting of the patent;
- c) the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request for the enforceable life of the patent, whichever is longer;
- d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and
- e) the deposit will be replaced if it should ever become inviable.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 55 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hensel et al (Cancer Research 59:5299-5306, 1999), in view of Vollmers et al (IDS, 1998).

The claims are drawn to a method for identifying a candidate therapeutic compound, the method comprising the steps of (a) contacting a cell expressing a polypeptide comprising the amino acid sequence of SEQ ID NO:6, with a test compound and (b) determining whether the test compound induces apoptosis of the cell, wherein a test compound that induces apoptosis of the cell and not a control cell is a candidate therapeutic compound, wherein the cell is adenocarcinoma cell line 23132. Claim 57, which depends on claim 55, indicates that the cell expressing a polypeptide comprising the amino acid sequence of SEQ ID NO:6 is adenocarcinoma cell line 23132.

Hensel et al disclose a test compound, antibody SC-1, that binds to the adenomacarcinoma cell line 23132 and induces apoptosis of that cell line (see Figure 5).

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Hensel et al does not specifically teach that antibody SC-1 does not induce apoptosis of control cells.

Vollmers et al, teaches that the antibody SC-1, does not induce apoptosis in normal tissues (p551, 1st column, 2nd paragraph).

One of ordinary skill in the art would have been motivated to apply Vollmers et al's teaching that SC-1 does not induce apoptosis of control cells to Hensel et al's teaching that SC-1 induces apoptosis of the cell line 23132 that expresses a polypeptide comprising the amino acid sequence of SEQ ID NO:6 because Hensel et al refers to the Vollmers et al paper as indicating that tumor cells can be selectively removed by a specific apoptotic signal. Thus, the antibody SC-1 can specifically induce apoptosis in tumor cells while not inducing apoptosis of the surrounding normal cells.

Summary

6. No claims allowed

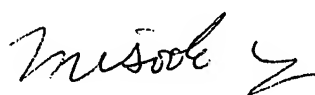
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halvorson, PhD whose telephone number is (571) 272-6539. The examiner can normally be reached on Monday through Friday from 8:30am to 5 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Halvorson, PhD
Patent Examiner
571-272-6539


MISOOK YU
PRIMARY EXAMINER